

Exhibit U



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-04 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE SECRETARY'S DECLARATION UNDER THE ACT OCTOBER 22, 2020, AS MODIFIED ON OCTOBER 23, 2020

The Office of the General Counsel (OGC) has received questions concerning the scope and meaning of “program planner” and “Authority Having Jurisdiction” under the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, and its implementing secretarial Declarations. This Advisory Opinion addresses:

1. Who is a program planner under the PREP Act and the Secretary’s March 10, 2020 Declaration, as amended (Declaration)?¹
2. What is the scope of the proviso in the Declaration limiting PREP Act coverage to, *inter alia*, activities authorized by an “Authority Having Jurisdiction”?

In this Advisory Opinion, OGC re-emphasizes the breadth of PREP Act immunity. It covers a broad range of entities when such entities take reasonable steps to follow public-health guidelines and directives in using covered medical products. Such entities are not limited to healthcare professionals and healthcare companies that are part of a government response to the COVID-19 pandemic. Such entities may also include businesses, schools, and places of worship.

I. ANALYSIS

A. BACKGROUND

COVID-19 is an unprecedented global challenge. As we learn more about the highly contagious pathogen that causes COVID-19, public-health guidance and directives tend to change to reflect the new knowledge. Those changes do not always occur uniformly or simultaneously among scientists and across America’s federal, state, territorial, tribal, local, and other public-health authorities—leading to uncertainty.

Those uncertainties present potential legal risk for public and private individuals and organizations as they combat the pandemic, restore and strengthen America’s economy, ensure that transportation remains available, and provide safe environments for education and worship. Unfortunately, such perceived risks may hinder those essential efforts.

They should not. The PREP Act exists, in part, to remove legal uncertainty and risk. When an individual or organization satisfies the requirements of the PREP Act and the Declaration, that “covered person” “shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.”²

¹ See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,202 (Mar. 17, 2020) (Declaration); 85 Fed. Reg. 21,012 (Apr. 15, 2020) (First Amendment); 85 Fed. Reg. 35,100 (June 8, 2020) (Second Amendment); 85 Fed. Reg. 52,136 (Aug. 24, 2020) (Third Amendment).

² 42 U.S.C. § 247d-6d(a)(1).

Under the PREP Act, the term “covered person” includes a broad range of individuals and organizations. The term includes, among other things, anyone who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including anyone who provides a facility to administer or use a covered countermeasure in accordance with the Declaration.

The term “covered countermeasure” generally includes products (1) that the Food and Drug Administration (FDA) has approved, cleared, licensed, or authorized for emergency or investigational use; and (2) that are used to address COVID-19 or associated health threats, including harms that COVID-19 might otherwise cause.

The Declaration broadly extends PREP Act immunity to, among other things, a covered person’s conduct relating to the administration or use of covered countermeasures according to applicable public-health guidance and directives during this declared emergency.³

As we have previously explained, when a person complies with all other requirements in the PREP Act and Declaration, PREP Act immunity applies if

- the person reasonably could have believed that the person was a covered person,
- the person reasonably could have believed that the product was a covered countermeasure, and
- the person did not engage in willful misconduct that proximately caused serious physical injury or death.⁴

This Advisory Opinion discusses the broad availability of that immunity in more detail. Specifically, we focus on (1) the definition of a “program planner” and (2) the activities authorized by an “Authority Having Jurisdiction.” This Advisory Opinion also provides examples of PREP Act coverage when a “program planner” follows the public-health guidance or directives of an applicable “Authority Having Jurisdiction”—even as guidance or directives change or they conflict with other guidance or directives.

B. PROGRAM PLANNERS

Under the PREP Act, the term “covered person” includes the United States or “manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees.”⁵

³ See 85 Fed. Reg. at 15,200 (affording liability immunity to “covered persons” for “recommended activities” related to activities authorized in accordance with the public-health and medical response of the Authority Having Jurisdiction).

⁴ See Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act (May 19, 2020), <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf> (last visited Oct. 23, 2020) (PREP Act Advisory Opinion); see also 42 U.S.C. § 247d-6d(a)(4)(B).

⁵ 85 Fed. Reg. at 151,199; 42 U.S.C. § 247d-6d(i)(2).

The PREP Act broadly defines a “program planner” using three elements: identity, function, and compliance.

Identity: A program planner is a state or local government, including an Indian tribe, a person employed by the State or local government, or other “person” who carries out the functions described immediately below. Under the PREP Act, a “person” includes “an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, state, or local government agency or department.”⁶

Function: A program planner performs certain functions, including “supervis[ing] or administer[ing] a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product.”⁷ The statute explains that those functions broadly include “establish[ing] requirements, provid[ing] policy guidance, or suppl[ying] technical or scientific advice or assistance or provid[ing] a facility to administer or use a covered countermeasure.”⁸

Compliance: Finally, to qualify as a program planner, the entity must perform those functions “in accordance with” the Declaration.⁹

The Declaration incorporates these definitions.¹⁰ The Declaration’s preamble further explains that a program planner can be a “private sector employer or community group” that “carries out the described activities.”¹¹ Nothing in the preamble or text of the Declaration limits the statutory definitions.

In short, any individual or organization can potentially be a program planner and receive PREP Act coverage. So for example, private businesses, public and private transportation providers, public and private schools, and religious organizations are all eligible for PREP Act coverage when they act in accordance with the PREP Act and the Declaration. It is important to remember, however, that the PREP Act does not provide immunity against federal enforcement actions.¹² And PREP Act immunity (but not preemption) is limited to claims for death, physical, mental or emotional injury, illness, disability or condition, fear of such harm or need for medical monitoring, and damage to property, including business interruption loss.¹³

⁶ 42 U.S.C. § 247d-6d(i)(5).

⁷ *Id.* at § 247d-6d(i)(6).

⁸ *Id.*

⁹ We use the term “entity” to include persons (*see* 1 U.S.C. § 1) and governmental units, whether state, tribal, local, or federal.

¹⁰ *See* 85 Fed. Reg. at 15,201.

¹¹ *Id.* at 15,199.

¹² *See* PREP Act Advisory Opinion at 2.

¹³ *See* 42 U.S.C. § 247d-6d; PREP Act Advisory Opinion.

C. AUTHORITY HAVING JURISDICTION

In order for there to be PREP Act coverage, there must be a PREP Act declaration.¹⁴ Among other things, such a declaration may specify whether PREP Act immunity “is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.”¹⁵

For the COVID-19 public-health emergency, section VII of the Declaration specifies that “liability immunity is afforded to Covered Persons *only* for Recommended Activities involving Covered Countermeasures that are related to” (1) federal agreements or (2) “[a]ctivities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.”¹⁶ An Authority Having Jurisdiction may authorize such activities through, among other things, guidance, requests for assistance, agreements, directives, or other arrangements (collectively guidance).¹⁷

Public-health guidance from an applicable Authority Having Jurisdiction that recommends or requires using covered countermeasures in certain circumstances may qualify as authorizations under the PREP Act and the Declaration. But to obtain such authorization, a covered person must follow that public-health guidance. The Declaration explains that the Authority Having Jurisdiction means the “public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, tribal, state, or federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.”¹⁸ Therefore, a covered person must comply with the public-health guidance issued by an Authority Having Jurisdiction over the person’s activity or location in order to qualify for PREP Act immunity.

If there are conflicts, PREP Act coverage will apply to a covered person using a covered countermeasure in accordance with *any* of the guidance. A conflict exists when (1) one guidance includes a recommendation or mandate that another guidance does not, and (2) there is no order of precedence under applicable law or in the guidance itself. If the applicable law or the guidance explains which authority takes precedence, a covered person must follow the guidance of the Authority Having Jurisdiction that takes precedence in order to obtain PREP Act coverage.

To illustrate, if a governor’s order on using face masks preempts or otherwise takes precedence over a mayor’s order under that state’s law, then the former must be the basis for PREP Act coverage. If one guidance says that it does not replace another guidance, the latter must be the basis for PREP Act coverage. For example, the Centers for Disease Control and Prevention’s (CDC) guidance for “Preparing for a Safe Return to School” specifies that “[t]his guidance is meant to supplement—not replace—any state, local, territorial, or tribal health and safety laws, rules, and regulations with which

¹⁴ See 42 U.S.C. § 247d-6d(a)(1).

¹⁵ 42 U.S.C. § 247d-6d(b)(2)(E).

¹⁶ See 85 Fed. Reg. at 15,202.

¹⁷ PREP Act Advisory Opinion at 2.

¹⁸ 85 Fed. Reg. at 15,202.

schools must comply.”¹⁹ So if there were a conflict between that CDC guidance and “any state, local, territorial, or tribal health and safety laws, rules, and regulations with which schools must comply,” a covered person must rely on guidance of the latter jurisdiction, and not CDC’s guidance, as the basis for PREP Act coverage.

If a guidance changes, the guidance in effect during the activity at issue will determine whether there is PREP Act coverage.

D. EXAMPLES

To illustrate more concretely the discussion above, we provide the following hypothetical examples of program planners using covered countermeasures according to the guidance of an Authority Having Jurisdiction. We use these examples to help illustrate only the PREP Act doctrines discussed above.

Testing: Federal, state, and local Authorities Having Jurisdiction issue conflicting guidance on how frequently to test at universities. Neither the state or federal law, nor the guidance from the state or federal Authorities Having Jurisdiction, preempts or supersedes the guidance from the local Authority Having Jurisdiction. A private university that has re-opened for in-person learning follows the guidance of the local Authority Having Jurisdiction in the geographic area where the university is located. The university uses a COVID-19 test that has received an Emergency Use Authorization (EUA) by the FDA. The local Authority Having Jurisdiction recommends a lower testing frequency than the state or federal Authorities Having Jurisdiction. A student who gets COVID-19 sues the university, claiming that its failure to follow the guidance from the state or federal Authority Having Jurisdiction caused the student’s injuries.

The university is a program planner because it has, among other things, “supervised or administered a program with respect to the administration … or use of a … qualified pandemic … product.”²⁰ By following the guidance of the local Authority Having Jurisdiction, the university has complied with the Declaration.

The university is immune from suit and liability for loss, assuming that it has satisfied all other requirements of the PREP Act and Declaration.

Face Masks: FDA has issued an EUA authorizing “the use of face masks, including cloth face coverings, as source control for use by members of the general public, as well as [health care personnel] in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.”²¹

¹⁹ *Preparing K-12 School Administrators for a Safe Return to School in Fall 2020*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/prepare-safe-return.html> (last visited Oct. 23, 2020).

²⁰ 42 U.S.C. § 247d-6d(i)(6).

²¹ *April 24, 2020 Letter to Manufacturers of Face Masks*, FDA, <https://www.fda.gov/media/137121/download> (last visited Oct. 23, 2020); *FAQs on the Emergency Use Authorization for Face Masks (Non-Surgical)*, FDA, <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorization-face-masks-non-surgical> (last visited Oct. 23, 2020).

CDC has issued guidance for “Grocery & Food Retail Workers.”²² In that guidance, “CDC recommends wearing cloth face coverings in public settings where other social distancing measures are difficult to maintain, especially in areas of significant community-based transmission.” The guidance also directs employers of grocery and food-retail workers to “[f]ollow *all* applicable local, state, and federal regulations and public health agency guidelines.”²³ A county department of health has issued a face-mask guidance recommending that those working inside a grocery store should wear cloth face covering *and* maintain social distancing.

Following CDC guidance, a grocery store in that county requires its workers to wear cloth face coverings in the public portions of its stores “where other social distancing measures are difficult to maintain.” A customer in that store gets COVID-19 and sues the grocery store, claiming that its failure to follow the county guideline contributed to the customer’s injuries.

Here, the CDC guidance directed the grocery store to follow all local, state, and federal regulations and public-health agency guidelines. The grocery store failed to follow the more stringent county guideline. Therefore, the grocery store does not have PREP Act immunity against the customer’s claim.

COVID-19 Vaccine Administration. CDC prioritizes certain populations to receive the COVID-19 vaccine while there are limited doses. A pharmacy prioritizes the CDC-designated populations for receiving the COVID-19 vaccine.

Because of that prioritization, someone seeks but does not receive the COVID-19 vaccine from the pharmacy because of the limited quantity of vaccine doses. That person gets COVID-19 and sues the pharmacy.

The pharmacy is a program planner, as set forth above. Administration of covered countermeasures, as defined in the Declaration, includes both “physical provision of the countermeasures to recipients” or “activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose[s] of distributing and dispensing countermeasures.”²⁴ Management and operation of countermeasure programs and decisions directly relating to public and private delivery, distribution, and dispensing of countermeasures involve decisions regarding prioritization of populations to receive countermeasures while there are limited doses. And prioritization necessarily entails temporarily withholding limited doses from some recipients, as directed by an Authority Having Jurisdiction.

By administering the COVID-19 vaccine pursuant to CDC prioritization, the pharmacy has complied with the guidance of an Authority Having Jurisdiction. The pharmacy has PREP Act coverage, assuming that it has also complied with all other requirements of the PREP Act and Declaration.

²² *What Grocery and Food Retail Workers Need to Know about COVID-19*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/grocery-food-retail-workers.html> (last visited Oct. 23, 2020).

²³ *Id.* (emphasis added).

²⁴ 85 Fed. Reg. at 15,202.

During the H1N1 pandemic, a New York court addressed a similar situation. In *Casabianca v. Mount Sinai Medical Center*, the court concluded that the PREP Act does not cover a provider that followed guidelines from CDC, the New York State Department of Health, and the New York City Department of Health. 1014 N.Y. Slip. Op. 33583(U), 2014 WL 10413521 (N.Y. Sup. Dec. 12, 2014). Under those guidelines, children, pregnant women, and hospital employees received priority for the H1N1 vaccine while there were shortages. The plaintiff's husband did not fit into any of those eligibility categories; hence, he did not receive the vaccine. The husband died after a surgical procedure and exposure to swine flu. His wife sued the provider. The court held that PREP Act immunity did not apply because it "only applies to the actual use of the vaccine." *Id.* at *4.

The court was wrong. As the court acknowledged, "administration" is broader than the "physical provision of a countermeasure to a recipient." *Id.* at *3. "Administration" also encompasses "activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities." *Id.*

Activities relating to management and operation of a vaccination program pursuant to an Authority Having Jurisdiction include following CDC directions on who to vaccinate when there are limited doses. If anything, following CDC directions on vaccination priority has a closer relationship to the use of the vaccine than decisions about security and queuing recipients of the vaccine, which may result in "slip and fall injuries and vehicle accidents that are connected to the vaccination process, be it at a retail store or some other facility." *Id.* at 4. The court recognized that PREP Act immunity can cover such injuries and accidents, but declined to interpret "activities related to management and operation of programs and locations for providing countermeasures to recipients" consistent with the plain meaning of that phrase. The plain meaning of "management and operation of programs for providing countermeasures" includes following CDC vaccine-prioritization guidelines. And if there were any doubt, the plain meaning of "activities related to" such management and operation is even broader. And that broader definition would certainly cover running a vaccination program pursuant to CDC guidelines, even assuming *arguendo* that "management and operation" does not.

II. Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.²⁵ It is not a final agency action or a final order. Nor does it bind the Department of Health and Human Services or the federal courts. It does not have the force or effect of law.

Persons seeking PREP Act immunity are responsible for determining whether their products are "covered countermeasures," whether a person or entity is a "covered person," whether reasonable

²⁵ See *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); Statement of Organization, Functions, and Delegations of Authority, 85 Fed. Reg. 54,581 54,583 (Sept. 2, 2020).

precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities. In order to obtain PREP Act coverage, persons must meet all requirements set forth in the PREP Act and the Declaration.

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October 23, 2020